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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/395,038	09/13/99	TRINCHIERI G	WST85USA ;

HM12/1206

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EXAMINER	
PRASAD, S	
ART UNIT	**PAPER NUMBER**
1646	7

DATE MAILED: 12/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/395,038	Trinchieri et. al.	
	Examiner	Art Unit	
	Sarada C Prasad	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-38 are drawn to

a) a method for enhancing the adjuvant effect of IL-12 (claims 1-15),

b) a method for reducing the immunosuppressive effects of IL-12 (claims 16-26),

c) a method for reducing the toxicity of IL-12 treatment (claims 27-38) by co-administering to a mammalian patient said IL-12, a vaccine antigen, and an effective amount of a nitric oxide inhibiting and/or neutralizing agent, classified in class 424 subclass 85.2.

Group II. Claims 39-41 are drawn to pharmaceutical compositions for use of IL-12, as an adjuvant, as a therapeutic agent along with a vaccine antigen and NO neutralizing agent, drawn to class 424 subclass 85.2.

Invention I and II are distinct each from the other because they do not require one for the practice of the other. For example, adjuvant action can be achieved by many compounds other than IL-12 (Group Ia), while approaches to reduction of immunosuppression of IL-12 (Group Ib) and reduction of toxicity of IL-12 (Group Ic) may also lead to reduction of its instant intended (cytokine or adjuvant) activity. In addition, pharmaceutical compositions containing IL-12 may also be used to obtain end results other than adjuvant action. For example, use of IL-12 as a marker for disease activity and possibly a prognosis in sarcoidosis has been reported.

These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter. Therefore, the search

required for Group I would not reveal the references required for Group II, restriction for examination purposes as indicated is proper.

Election of Species:

In addition, inventions I-II also contain claims drawn to the following patentably distinct species:

Generic claims 1,16, 27 recite lists of NO inhibiting, reducing, neutralizing compounds in addition to those regulating NO synthase activity consists of several derivatives of arginine, indazole, guanidine, citrulline among many others and are drawn to class/subclass undeterminable. Each of these compounds has more than one type of effects and the same effect can be observed with other compounds also. For example, infusion of 1-NAME claimed as a NO synthase inhibitor, in the instant invention, can also be used to abolish sildenafil-induced pulmonary vasodialation. Furthermore, antisense oligonucleotide designed against the complementary DNA to human inducible NO synthase are employed to inhibit translation of NO synthase mRNA in human vascular endothelial cells.

Therefore, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 16, 27 are generic. Upon election for restriction, the generic claims will be examined to the extent they read on the elected species of NO reducing compounds.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner
Art Unit 1646
October 5, 2000

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER